Table of Contents

	Introduction	
Section 2.	Analyzer Components	;
	Analyzer Flow Diagram	
	Analyzer Component Illustrations	
	Analyzer Settings	
	Screen Navigation	
	Initial Screen	
	Main Menu Screen	
	"Options Menu" Screen	6
	"Database Menu" Screen	
	"Unit" Screen	
	"Printer Setup" ("PRT Setup") Screen	
	"Self Test Results" Screen	
	Keyboard Shortcuts	
	Analyzer Setup	
	Step 1. Printer Setup	
	Step 2. Unit Setup	
	Step 3. Clock Setup	È
	Step 4. Language SetupStep 5. "Type of Strip" Selection	. I(
	Step 6. Clinical Number Setup	. I(11
	Step 7. Single Test Mode or Continuous Test Mode Selection	. I(11
0 41 4		
	Operation Instructions	
	Step 1. Turn on the Analyzer to Initiate Self-Inspection	. 12
	Step 2. Select Analyzer Settings and Prepare Test Materials	. 12
	Step 3. Perform the Test and Obtain Results	
Section 5.	Database and Memory	.16
	Locate Clinical Numbers and View Records in Database	.16
	Step 1. Navigate to the "Database Menu"	.16
	Step 2. Locate Clinical Records	.16
	Step 3. View Current, Previous, and Next Record	.17
	Export Database	
	Memory	
	Clear Memory	
	Data Communication	
	Quality Control	
Section 8. I	Maintenance	.19
	Precautions	
	Daily Cleaning	.19
	Step 1. Remove the Strip Holder	.19
	Step 2. Clean the Strip Holder	.19
	Step 3. Load the Strip Holder	.19
	Step 4. Return the Strip Holder to the Original Position	.20
	Uric Alkali Cleaning	
	Sterilizing Process	
Section 9. I	Manual Self-Test and Troubleshooting	.2
	Manual Self-Test	
	Troubleshooting Table	.22
Appendix 1	I. Urine Analyzer Specifications and Compatible Urinalysis Reagent Strips	.23
Appendix 2	2. Urinalysis Reagent Strip Specifications and Result Print-Out	.24
Appendix 3	3. Catalog	.2
	4. Index of Symbols	
	5. Warranty	

Section 1. Introduction

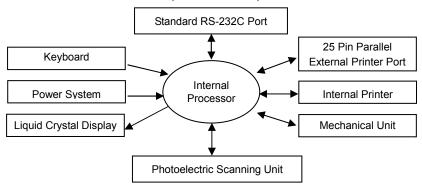
The *Mission*™ U120 Urine Analyzer is a reflectance photometer that analyzes the intensity and color of light reflected from the reagent areas of a urinalysis reagent strip. Without a urine analyzer, operators must visually compare the reagent areas of the strip to a color chart using the naked eye. Therefore, visual determination for urinalysis is a time consuming task. Additionally, visual testing is prone to inaccuracy due to human misinterpretation and variable light sources. To minimize the variability associated with visual testing, the *Mission*™ U120 Urine Analyzer is specifically designed for improved accuracy and efficiency of urinalysis featuring data management and report generation capabilities.

The *Mission*™ U120 Urine Analyzer utilizes modern optics, reliable electronics, and easy to operate software. Using a light emitting diode (LED) as a light source and a photodiode as a light sensor, the advanced optical system provides operators with accurate results. The internal electronics are configured in a modular integrated circuit design to minimize electromagnetic interference and ensure reliability. The software is designed to maximize analyzer functionality with minimal training. The analyzer is also capable of adjusting specific gravity results based on the measured urinary pH to account for variance in ionic concentrations. In addition, the analyzer features automatic calibration and self-inspection capabilities for accurate readings. Together, these features provide reliable results and improved efficiency in urinalysis testing.

Section 2. Analyzer Components

Analyzer Flow Diagram

The analyzer is composed of an Internal Processor with Memory, Mechanical Unit, Liquid Crystal Display (LCD), Photoelectric Scanning Unit, Power System, Keyboard, 25 Pin Parallel External Printer Port, Internal Printer, and Standard RS-232C Port.

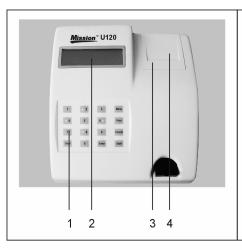


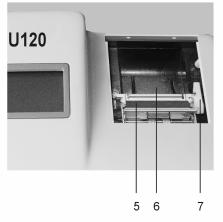
The core component of the analyzer is the Internal Processor, which is capable of sending, receiving, processing, and recording signals from the various components as shown above. The Keyboard enables the operator to control the analyzer and access information stored in the memory database. The Liquid Crystal Display (LCD) allows the operator to view the numerous screens and the Power System provides the proper power for the analyzer to operate. The Photoelectric Scanning Unit is designed to illuminate the strip and analyze the reflected light. The Mechanical Unit moves the Strip Holder in position for the Photoelectric Scanning Unit to analyze the strip. The Internal Printer prints the urinalysis results for the operator's records. The Standard RS-232C Port and 25 Pin Parallel External Printer Port allow the analyzer to communicate with external computers and printers.

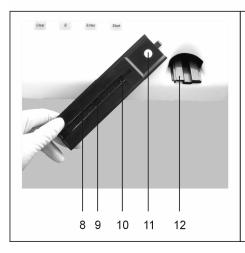
Analyzer Component Illustrations

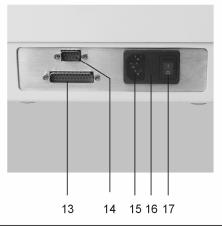
- 1. Keyboard
- 2. Liquid Crystal Display
- 3. Printer Cover
- 4. Printer Paper Access Slot
- 5. Printer Roller
- 6. Printer Paper Roll Container
- 7. Printer Lever
- 8. Strip Holder
- 9. Strip Holder Channel

- 10. Strip Holder Backstop
- 11. White Calibration Circle
- 12. Strip Holder Mount
- 13. 25 Pin Parallel External Printer Port
- 14. Standard RS232C Port
- 15. Power Socket
- 16. Fuses
- 17. Power Switch









Section 3. Analyzer Settings

Screen Navigation

Follow the instructions below to navigate the analyzer's menus.

Initial Screen

The Initial Screen as shown below appears upon completion of the Automatic Self-Inspection whenever the analyzer is turned on.

Note: Return to the Initial Screen at any time by using the arrow keys on the keyboard and selecting "Exit" from any other screen or pressing the Cancel key on the "Place a strip on the holder" Screen.

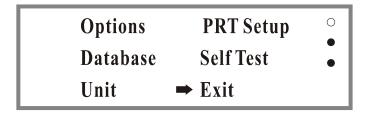


- The date, time, model and version number are indicated on the Initial Screen.
- The three circles on the right side of the Initial Screen indicate the status of the analyzer: Continuous or Single Test Mode (top circle), Auto-Print or Manual Print Mode (middle circle), and Printer Paper Present or Printer Paper Empty (bottom circle).

Position	Function	On-Screen Symbol
	Continuous Test Mode	•
Top Circle	Single Test Mode	0
	Auto-Print Mode	•
Middle Circle	Manual Print Mode	0
	Printer Paper Present	•
Bottom Circle	Printer Paper Empty	Flashing •

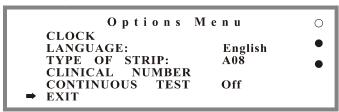
Main Menu Screen

- From the Initial Screen or the "Place a strip on the holder" Screen:
 Press the Menu key on the keyboard to navigate to the Main Menu Screen,
 shown below.
- From any other screen:
 Use the arrow keys on the keyboard to select "Exit" to navigate to the Main Menu Screen.



"Options Menu" Screen

 Use the arrow keys on the keyboard to select "Options" from the Main Menu Screen, then press the Enter key on the keyboard to navigate to the "Options Menu" Screen, shown below.



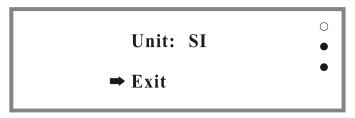
"Database Menu" Screen

 Use the arrow keys on the keyboard to select "Database" from the Main Menu Screen, then press the Enter key on the keyboard to navigate to the "Database Menu" Screen, shown below.



"Unit" Screen

 Use the arrow keys on the keyboard to select "Unit" from the Main Menu Screen, then press the Enter key on the keyboard to navigate to the "Unit" Screen, shown below.



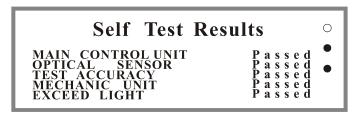
"Printer Setup" ("PRT Setup") Screen

 Use the arrow keys on the keyboard to select "PRT Setup" from the Main Menu Screen, then press the Enter key on the keyboard to navigate to the "Printer Setup" Screen, shown below.



"Self Test Results" Screen

 Use the arrow keys on the keyboard to select "Self Test" from the Main Menu Screen, then press the Enter key on the keyboard to navigate to the "Self Test Results" Screen, shown below.



Keyboard Shortcuts

Use the following keyboard shortcuts from the Main Menu Screen to quickly change analyzer settings.

Keyboard Shortcut	Function	On-Screen Symbol	
1	Continuous Test Mode	•	
'	Single Test Mode	0	
3	Auto-Print	•	
3	Manual Print	0	
5	Clinical Number		
7	Locate Patient Record		
9	Begin Analyzer Self-Test		

Analyzer Setup

Follow the instructions below to set up the Printer, Unit, Clock, Language, Clinical Number, Type of Strip, and Test Mode.

Step 1. Printer Setup

Use Printer Setup to select printing capabilities.

Load Printer Paper

Use the provided paper roll to load the printer paper in the Internal Printer.

 Remove the Printer Cover by pushing down the bottom Printer Cover and lifting up the top.

- 2. Place the new paper roll into the Printer Paper Roll Container and unwind the roll so the paper can easily unroll.
- 3. Pull the green Printer Lever towards the Strip Holder to allow the paper to be fed through.
- Feed the paper under the black Printer Roller and pull the paper up as shown below. Leave about 10 cm (4 inches) of extra paper above the Printer Roller.
- 5. Return the Printer Lever to its original position.
- 6. Thread the excess paper through the Printer Paper Access Slot.
- 7. Return the Printer Cover to its original position and snap it firmly in place.



Select Printer Settings

Change Printer Settings to switch between Internal or External Printers, Expand or Normal Font Size, and Auto-Printing or Manual Printing.

Internal or External Printer

Select Internal or External Printer.

- Press the up arrow key (↑) on the keyboard to select "PRT Setup" from the Main Menu Screen, then press the Enter key on the keyboard.
 Note: Refer to Main Menu Screen on page 5 to navigate to the Main
 - Menu Screen.

 Menu Screen the up arrow key (*) on the keyboard to coloct "PRINTER SELECT"
- Press the up arrow key (↑) on the keyboard to select "PRINTER SELECT".
 The current setting will be displayed next to the "PRINTER SELECT" setting.
- Press the Enter key on the keyboard to select "Internal" or "External" printer.
 - Note: The Internal Printer is built into the analyzer. An External Printer can be connected with a printer cable to the External Printer Port on the back of the analyzer.

Expand or Normal Font Size

Select Expand or Normal Font Size.

- Use the down arrow key (↓) on the keyboard to select "PRINTER MODE" from the "Printer Setup" Screen. The current setting will be displayed next to the "PRINTER MODE" setting.
 - Note: Refer to **Printer Setup** on page 7 to navigate to the "Printer Setup" Screen.
- 2. Press the Enter key on the keyboard to select "Expand" or "Normal" font size.

Note: Select "Normal" to conserve printer paper. When "Expand" is selected, paper is consumed more quickly due to the larger font size.

Auto-Printing or Manual Printing

Select Auto-Printing or Manual Printing.

- Press the down arrow key (↓) on the keyboard to select "AUTOPRINT" from the "Printer Setup" Screen. The current setting will be displayed next to the "AUTOPRINT" setting.
 - Note: Refer to **Printer Setup** on page 7 to navigate to the "Printer Setup" Screen.
- Press the Enter key on the keyboard to select "On" or "Off". Note:
 - Single Test Mode/Continuous Test Mode: If "On" is selected, every test result will be printed automatically.
 - Single Test Mode: If "Off" is selected, the operator must manually press the Print key on the keyboard for each test result to be printed.
- Press the down arrow key (↓) on the keyboard to select "EXIT" then press the Enter key to return to the Main Menu Screen.

Step 2. Unit Setup

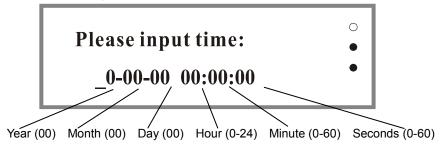
Select Standard International (SI) or Conventional Units.

- Press the left arrow key (←) on the keyboard to select "Unit" from the Main Menu Screen, then press the Enter key.
 - Note: Refer to **Main Menu Screen** on page 5 to navigate to the Main Menu Screen.
- Press the up arrow key (↑) on the keyboard to select "Unit" then press the Enter key to select either Standard International (SI) or Conventional Units. Note: Arbitrary results will be printed automatically regardless of the unit setting selected.
- Press the down arrow key (↓) on the keyboard to select "Exit" then press the Enter key to return to the Main Menu Screen.

Step 3. Clock Setup

Set up the correct date and time.

- Press the up arrow key (↑) on the keyboard to select "Options" from the Main Menu Screen, then press the Enter key to navigate to the "Options Menu" Screen.
 - Note: Refer to **Main Menu Screen** on page 5 to navigate to the Main Menu Screen.
- 2. Press the up arrow key (↑) on the keyboard to select "CLOCK" then press the Enter key to view the screen shown below.



- 3. Use the number keys on the keyboard to type in the current date and time as shown in the following example: 05-08-12 13:30:00 (indicating August 12th, 2005 1:30PM). If the information is typed incorrectly, press the Clear key on the keyboard to start retyping information again. Then press the Enter key when the correct date and time have been typed in. The new date and time will be shown on the Initial Screen.
 - Note: To abort changes, press the Cancel key on the keyboard to keep the current setting.
- 4. Continue with analyzer setup, or press the Enter key on the keyboard to select "EXIT" and return to the Main Menu Screen.

Step 4. Language Setup

Select English or Spanish to be displayed on the screen.

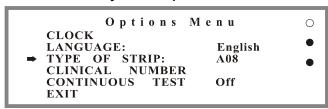
- 1. Press the up arrow key (↑) on the keyboard to select "LANGUAGE" from the "Options Menu" Screen. The current setting will be displayed next to the "Language" setting.
 - Note: Refer to "Options Menu" Screen on page 6 to navigate to the "Options Menu" Screen.
- 2. Press the Enter key on the keyboard to select "English" or "Spanish".
- 3. Continue with analyzer setup, or press the Enter key on the keyboard to select "EXIT" and return to the Main Menu Screen.

Step 5. "Type of Strip" Selection

Select the type of strip to be tested.

- Press the down arrow key (↓) on the keyboard to select "TYPE OF STRIP" from the "Options Menu" Screen. The current type of strip will be displayed next to the "TYPE OF STRIP" setting.
 - Note: Refer to "Options Menu" Screen on page 6 to navigate to the "Options Menu" Screen.
- Press the Enter key on the keyboard to select the "A08" for 8 parameters, "A09" for 9 parameters, "A10" for 10 parameters or "A11" for 11 parameters. Refer to Compatible Urinalysis Reagent Strips on page 23 for a detailed list of analytes.

Note: Ensure that the type of strip selected corresponds with the strip to be used. Use of any other strip will cause incorrect results.



 Continue with analyzer setup, or press the down arrow key (↓) on the keyboard to select "EXIT" then press the Enter key to return to the Main Menu Screen.

Step 6. Clinical Number Setup

Assign the clinical number for recording specimen results.

 Press the down arrow key (↓) on the keyboard to select "CLINICAL NUMBER" from the "Options Menu" Screen.

- Note: Refer to "Options Menu" Screen on page 6 to navigate to the "Options Menu" Screen.
- Press the Enter key to display the "Old number". The default setting is 000001.
- Use the number keys to type in the "New number" by using 1-6 digits. Note:
 - The highest clinical number is 999999. After the clinical number reaches 999999, it reverts to 000000.
 - If incorrect clinical number is typed, press the Clear key on the keyboard to retype the information.
 - If the clinical number shown on the "Old number" Screen does not need to be changed, press the Cancel key on the keyboard.

Warning: Entering a new number can potentially erase existing data if the clinical numbers overlap.

- Press the Enter key on the keyboard to return to the "Options Menu" Screen.
- Continue with analyzer setup, or press the down arrow key (↓) on the keyboard to select "EXIT" then press the Enter key to return to the Main Menu Screen.

Step 7. Single Test Mode or Continuous Test Mode Selection

Select Single Test Mode for low throughput analysis or Continuous Test Mode for high throughput analysis.

Description of Single Test Mode and Continuous Test Mode

- Single Test Mode: Continuous Test Mode in the "Off" position. This mode is recommended for analyzing one strip at a time. The throughput for the Single Test Mode is 40 tests/hour.
- Continuous Test Mode: Continuous Test Mode in the "On" position. This
 mode is recommended for continuously analyzing numerous strips one
 directly after another. The throughput for the Continuous Test Mode is
 120 tests/hour.

Select Single Test Mode or Continuous Test Mode

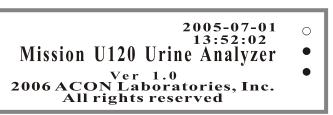
- Press the up arrow key (↑) on the keyboard to select "CONTINUOUS TEST" Mode from the "Options Menu" Screen. The current test mode will be displayed next to the "CONTINUOUS TEST" Mode setting.
 - Note: Refer to "Options Menu" Screen on page 6 to navigate to the "Options Menu" Screen.
- Press the Enter key on the keyboard to select the "On" position for Continuous Test Mode or "Off" position for Single Test Mode.
- 3. Press the Start key on the keyboard to begin testing.

Section 4. Operation Instructions

Step 1. Turn on the Analyzer to Initiate Self-Inspection

Observe the Automatic Self-Inspection when the analyzer is turned on to ensure the unit is functioning correctly.

- 1. Turn on the Power Switch. The Automatic Self-Inspection will automatically start by moving the Strip Holder out and back in.
- 2. Check the Self-Inspection results:
 - If the Automatic Self-Inspection passes, the Initial Screen will be displayed as shown below indicating the analyzer is functioning properly.



• If the Automatic Self-Inspection fails, a "Failed" Screen will be displayed as shown below indicating the source of the failure. Refer to **Troubleshooting Table** on page 22 to correct the failure.



Step 2. Select Analyzer Settings and Prepare Test Materials

Select the "Type of Strip", "Continuous Test" Mode or "Single Test" Mode, and "Clinical Number" to customize analyzer settings.

- Press the Menu key on the keyboard to customize the settings including "Type
 of Strip", "Continuous Test" Mode or "Single Test" Mode, and "Clinical Number"
 as necessary. Or press the Start key on the keyboard to use the current
 settings.
 - Note: Refer to **Analyzer Setup** on page 7 to customize settings. The default settings for first time operation are set by the manufacturer. After the first use, any changes made to the settings will be saved and used for future operations.
- 2. Allow the strip, urine specimen, and/or controls to reach room temperature at 15-30°C (59-86°F) prior to testing.
 - **Note:** Only use strips of the same brand as the analyzer to ensure proper function and accurate results.
- Remove the strips from the closed canister and use them as soon as possible. Immediately close the canister tightly after removing the required number of strips.

Step 3. Perform the Test and Obtain Results

Immerse the strip and obtain results using Single Test Mode or Continuous Test Mode.

Measuring in Single Test Mode

Use Single Test Mode to analyze urine specimens one at a time. Refer to **Single Test Mode or Continuous Test Mode Selection** on page 11 for instructions on selecting Single Test Mode.

 Press the Start key on the keyboard to fully extend the Strip Holder. The "Place a strip on the holder" Screen will be displayed as shown below.



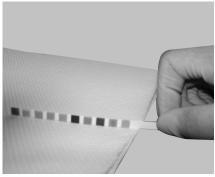
Press the Start key on the keyboard and wait for the audible triple beep to begin immersing the strip.

Note: Once the Start key is pressed, the countdown clock on the bottom right screen will start to count down from "65" and the operator will have 3 seconds before the triple beep signals the operator to immerse the strip into the urine specimen.

Upon hearing the triple beep and/or seeing the countdown clock reach "62", completely immerse the reagent areas of the strip in fresh, well-mixed urine and immediately remove the strip to avoid dissolving the reagents.



4. While removing the strip from the urine, run the edge of the strip against the rim of the urine specimen container to remove excess urine. Hold the strip in a horizontal position and bring the edge of the strip into contact with an absorbent material (e.g. a paper towel) to avoid mixing chemicals from adjacent reagent areas and/or soiling hands with urine.



 Place the strip with the reagent area facing upwards onto the Strip Holder Channel and make sure the strip end is touching the Strip Holder Backstop as shown below.



Note:

- When the countdown clock on the display reaches "1", the Strip Holder will carry the strip inside and begin analysis.
- The analyzer performs an automatic calibration each time a test is run.
- The results will be displayed on the screen and recorded in the memory automatically.
- The results will be automatically printed if the "Auto-Print" mode is turned on. If the "Auto-Print" mode is turned off, the operator must press the Print key on the keyboard to print the results.
- 6. Remove the used strip from the Strip Holder once it moves out. Dispose the used strip according to local regulations.
- 7. Repeat points 2-6 as described above to test additional urine specimens.
- 8. Perform daily cleaning when analysis is completed for the day. Refer to **Daily Cleaning** on page 19.

Measuring in Continuous Test Mode

Use Continuous Test Mode to analyze large numbers strips one directly after another. Refer to **Single Test Mode or Continuous Test Mode Selection** on page 11 for instructions on selecting Continuous Test Mode.

- 1. Press the Start key on the keyboard to fully extend the Strip Holder. The "Place a strip on the holder" Screen will be displayed.
- 2. Press the Start key on the keyboard and wait for the audible triple beep to

begin immersing the strip.

Note: Once the Start key is pressed, the countdown clock on the bottom right screen will start to count down from "65" and the operator will have 3 seconds before the triple beep signals the operator to immerse the strip into the urine specimen.

- 3. Upon hearing the triple beep and/or seeing the countdown clock reach "62", completely immerse the reagent areas of the strip in fresh, well-mixed urine and immediately remove the strip to avoid dissolving the reagents.
- 4. While removing the strip from the urine, run the edge of the strip against the rim of the urine specimen container to remove excess urine. Hold the strip in a horizontal position and bring the edge of the strip into contact with an absorbent material (e.g. a paper towel) to avoid mixing chemicals from adjacent reagent areas and/or soiling hands with urine.
- Place the strip with the reagent area facing upwards onto the Strip Holder Channel and make sure the strip end is touching the Strip Holder Backstop as shown above.
- 6. After hearing the next triple beep and/or seeing the countdown clock reaches "32", immerse a new strip in fresh, well-mixed urine, and repeat points 3-4 as described above. Then lay the new strip on a paper towel with the reagent areas facing upward and wait for the Strip Holder to move out.
- 7. After hearing the next triple beep and/or seeing the countdown clock reach "2", immerse a new strip in fresh, well-mixed urine, and repeat points 3-4 as described above. Then lay the new strip on a paper towel with the reagent areas facing upward and wait for the Strip Holder to move out.
 Note:
 - When the countdown clock on the display reaches "1", the Strip Holder will carry the strip inside and begin analysis while the countdown clock returns to "30". Then the results will be displayed on the screen and recorded in the memory automatically.
 - The results will be automatically printed if the "Auto-Print" mode is turned on.
- 8. Remove the used strip from the Strip Holder after the reading is complete and the Strip Holder moves out, then immediately place the new strip on the Strip Holder before the countdown clock on the display reaches "1" and the Strip Holder carries the new strip inside and begins analysis. Note:
 - Before the countdown clock on the display reaches "1" and the Strip Holder moves back in and analysis begins, the operator will have about 8 seconds to dispose the used strip and place the new strip on the Strip Holder.
 - After the first time the countdown clock reaches "1", it will return to "30" instead of "65" for all following strips. A triple beep will follow every 30 seconds, prompting the operator to immerse a new strip.
 - Dispose the used strip according to local regulations.
- 9. Repeat points 7-8 above to test additional urine specimens.
- When all specimens have been tested, press the Cancel key on the keyboard to stop testing.
- Perform daily cleaning when analysis is completed for the day. Refer to **Daily** Cleaning on page 19.

Section 5. Database and Memory

Locate Clinical Numbers and View Records in Database

Find and review Clinical Records stored in the analyzer.

Step 1. Navigate to the "Database Menu"

Open the "Database Menu".

Use the arrow keys on the keyboard to select "Database" from the Main Menu Screen then press the Enter key on the keyboard to view the "Database Menu", shown below.

Note: Refer to **Main Menu Screen** on page 5 to navigate to the Main Menu Screen.



Step 2. Locate Clinical Records

Search for Clinical Records in the Database.

- 1. Press the up arrow key (↑) on the keyboard to select "LOCATE" from the "Database Menu" Screen, shown above.
- 2. Press the Enter key on the keyboard to view the screen, shown below.



- Use the number keys on the keyboard to type in the desired clinical number then press the Enter key to view the results. Note:
 - Press the Clear key on the keyboard to erase mistyped clinical numbers then type in the correct clinical number.
 - If there is no record found in the database after typing in a specific clinical number, the "Record not found!" Screen will be displayed.
 Press any key on the keyboard to return to the "Database Menu" Screen.
- 4. Press the Print key on the keyboard to print the displayed record.
- 5. Press the left arrow key (←) or the up arrow (↑) on the keyboard to view the previous record, or press the right arrow key (→) or the down arrow key (↓) on the keyboard to view the next record. Then press the Print key on the keyboard to print the record displayed on the screen.
- Press the Cancel key on the keyboard to return to the "Database Menu" Screen and repeat Locate Clinical Records to locate a different clinical number as described above

Step 3. View Current, Previous, and Next Record

View and Navigate through a list of Clinical Records in the database.

- Use the arrow keys on the keyboards to select "CURRENT RECORD", "PREVIOUS RECORD", or "NEXT RECORD" then press the Enter key on the keyboard to review and print records as needed.
 - Note: The same operation may be completed by following point 5 **Locate Clinical Records** on page 16.
- Press the Cancel key on the keyboard to return to the "Database Menu" Screen, then use the arrow keys to select "EXIT" to return to the Main Menu Screen.

Export Database

To export the database, connect a RS-232C Cable from a computer to the Standard RS-232C Port on the back of the analyzer. The cable and software will enable all of the data to be stored on an external database on the computer where data manipulation and extended network sharing are possible.

Memory

Store up to 500 records which can be recalled at any time.

All test results will be automatically recorded in the memory. The memory can store up to 500 records. To ensure data security and utilize maximum memory capacity, always use a clinical number that is sequential to the previous test's clinical number.

Caution:

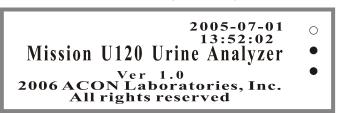
- The database will overwrite previously stored clinical records if the number of records exceeds 500. If there are already 500 records in the memory, the oldest record will be erased. For example, the 501st record will replace the 1st record in the memory.
- If the clinical number is changed and a clinical number is the same as a
 previous clinical number recorded in the memory, the previous clinical
 number's data in the memory will be erased and the record will be replaced
 with the new data.

Clear Memory

Erase the entire memory in the database.

1. Navigate to the Initial Screen, shown below.

Note: Refer to Initial Screen on page 5 to navigate to the Initial Screen.



Press the Clear key on the keyboard and the "CLEAR THE DATA" Screen will be displayed, shown below.

CLEAR THE DATA?

Press ENT key to confirm

Press the Enter key on the keyboard to clear the memory, or press any other key to exit the screen without erasing the existing memory.

Caution: If the Enter key on the keyboard is pressed, an audible quadruple beep will sound, indicating that the database has been cleared and no records can be recovered. The default clinical number will revert to 000001.

Section 6. Data Communication

The analyzer is equipped with two communication ports including a 25 Pin Parallel External Printer Port and a Standard RS-232C Port.

The analyzer requires an external printer with cable to print externally. Refer to **Internal** or **External Printer** on page 8 to use an external printer.

The analyzer requires a RS-232C Cable connected to a computer with the software installed to export the database. The cable and software will enable all of the data generated during testing to be stored in an external database on the computer where data manipulation and extended network sharing are possible. Refer to **Export Database** on page 17 for details.

Section 7. Quality Control

For best results, performance of reagent strips should be confirmed by testing known positive and negative specimens/controls whenever a new test is performed or whenever a new canister is first opened. Each laboratory should establish its own goals for adequate standards of performance.

Section 8. Maintenance

Precautions

Follow the precautions listed below to ensure accurate results and analyzer durability.

- Keep the analyzer away from direct sunlight and magnetic fields when testing to ensure accuracy of test results.
- Never place anything in the front of the Strip Holder to avoid collisions when the Strip Holder moves out.
- Keep the analyzer clean and wipe it frequently with a soft, clean and dry cloth.
 Use fresh water when needed.
- Do not clean the analyzer with substances such as gasoline, paint thinner, benzene compounds or other organic solvents to avoid any damage to the Strip Holder, White Calibration Circle, or other components.
- Do not wash the Liquid Crystal Display with water. To clean it, lightly wipe it
 with a clean, soft and dry rag or paper towel.
- The Strip Holder must be kept clean. Wipe using fresh water daily. Refer to Daily Cleaning on page 19.
- Follow proper precautions and all local regulations when disposing of the analyzer and used accessories.
- Do not use the analyzer or strips outside of the operating temperature ranges listed below to ensure accuracy of test results:
 - Analyzer: 0-40°C (32-104°F)
 - Strips: 15-30°C (59-77°F)

Daily Cleaning

Follow the instructions below after testing is completed every day.

Step 1. Remove the Strip Holder

- 1. Press the Start key on the keyboard to fully extend the Strip Holder.
- 2. Turn off the Power Switch after the Strip Holder is fully extended.
- Pull the Strip Holder backwards gently by the two sides of the Strip Holder as shown below.

Step 2. Clean the Strip Holder

- Clean the Strip Holder daily using a cotton swab or cotton ball with distilled water then dry with a clean, dry cotton ball.
- Examine the White Calibration Circle daily to ensure that there are no nicks or dirt present. Clean the White Calibration Circle periodically using a cotton swab or cotton ball with distilled water then dry with a clean, dry cotton ball.

Note: The White Calibration Circle should be replaced if any nicks or irremovable dirt are found. Please contact your local distributor if any nicks or irremovable dirt are found in the White Calibration Circle.

Step 3. Load the Strip Holder

- Grasp the Strip Holder as shown below.
- 2. Insert the Strip Holder into the Strip Holder Mount.

Note: When correctly positioned, the Strip Holder will snap and be locked in place, and the White Calibration Circle will not be visible. See illustration below.





Step 4. Return the Strip Holder to the Original Position

- Turn on the Power Switch.
- 2. Wait for the Strip Holder to start moving inside the analyzer.
- Turn off the Power Switch when the Strip Holder is inside the analyzer, or begin testing strips by referring to **Operation Instructions** on page 12.

Uric Alkali Cleaning

Follow the instructions below when Uric Alkali buildup is present.

- 1. Remove the Strip Holder by following **Remove the Strip Holder** on page 19.
- Clean the Strip Holder using a cotton swab or cotton ball with 0.1 N NaOH.
 Warning: Do not allow the NaOH solution to touch the White Calibration Circle.
- Clean the excess NaOH off the Strip Holder using a cloth moistened with distilled water.
- 4. Dry the Strip Holder with a clean and dry cotton ball.
- Load the Strip Holder and return the Strip Holder to the original position as described on page 20.

Sterilizina Process

Follow the instructions below to sterilize the Strip Holder when urine specimens come in contact with the Strip Holder.

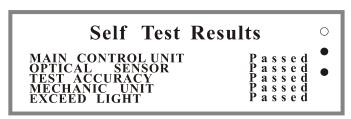
- 1. Remove the Strip Holder and repeat **Daily Cleaning** on page 19.
- 2. Clean the Strip Holder using a cotton swab or cotton ball with one of the following sterilizing solutions:
 - 2% Glutaraldehyde (sufficient density): Refer to the detailed instructions on the product label.
 - 0.05% Sodium Hypochlorite Solution: Add 1 mL 5% Sodium Hypochlorite into 99 mL distilled water, or prepare a 1:100 dilution ratio with a different final volume.
 - Isopropyl alcohol (70-80%).
- 3. Pour the sterilizing solution into a narrow vessel 10 cm (4 inches) high.
- 4. Dip the Strip Holder into the sterilizing solution and make sure to keep the White Calibration Circle out of the solution.
- 5. Soak the Strip Holder in the sterilizing solution for 10 minutes.
- 6. Take the Strip Holder out, clean and dry it.
- Load the Strip Holder and return the Strip Holder to the original position as described on page 20.

Section 9. Manual Self-Test and Troubleshooting

Manual Self-Test

An internal diagnostic is incorporated in the analyzer to help in the troubleshooting process.

- Press the up arrow key (↑) on the keyboard to select "Self Test" from the "Main Menu" Screen.
 - Note: Refer to **Main Menu Screen** on page 5 to navigate to the Main Menu Screen.
- Press the Enter key on the keyboard to begin the Manual Self-Test. The Strip Holder moves in and out twice and the Self-Test results will be displayed as shown below.



Note:

- If the analyzer is functioning properly, "Passed" will be displayed next to each of the tests as shown above.
- In the event of a malfunction, "Failed" will be displayed next to the respective test and the operator should refer to the **Troubleshooting Table** below for the solution.
- 3. Press any key on the keyboard to return to the Main Menu Screen.

Troubleshooting Table

The following table indicates the solutions for each problem.

Problem	Solutions
Strip position improper !	Adjust the strip so the strip end is completely touching the Strip Holder Backstop and centered in the Strip Holder Channel Check to see if the Strip Holder is positioned correctly on the Strip Holder Mount
Strip Missing!	Insert strip
No display on screen Fuse is damaged	Turn on the Power Switch Examine the Fuse on the back of the analyzer to determine if it is damaged and replace it if necessary Turn off the Power Switch.
i use is damaged	Disconnect the plug then replace the damaged Fuse with a new 2.0A Fuse
Printer does not work	 Set "Auto-Print" to the "On" position. Refer to Printer Setup on page 7 Load paper if necessary Ensure the Printer Setup is set for "Internal" if an external printer is not connected. Refer to Printer Setup on page 7 Clean with ethanol (C₂H₆O)
MAIN CONTROL UNIT Pailed •	Turn the Power Switch off then back on and perform a Self-Test. Refer to Manual Self-Test on page 21
OPTICALSENSOR • Failed •	 Ensure the Strip Holder is positioned correctly on the Strip Holder Mount. Refer to Daily Cleaning, Step 3 on page 19 Clean the Strip Holder. Refer to Daily Cleaning, Step 2 on page 19 Turn the Power Switch off then back on and perform a Self-Test. Refer to Manual Self-Test on page 21
TESTACCURACY • Failed •	Turn the Power Switch off then back on and perform a Self-Test. Refer to Manual Self-Test on page 21
MECHANIC UNIT Failed	Remove any obstacles in the path of the Strip Holder Do not touch the Strip Holder when it is moving Turn the Power Switch off then back on and perform a Self-Test. Refer to Manual Self-Test on page 21
EXCEED LIGHT • Failed •	Turn the Power Switch off then back on and perform a Self-Test. Refer to Manual Self-Test on page 21 To proceive additional technical support if you are unable to

Please contact your local distributor to receive additional technical support if you are unable to resolve the problems.

Appendix 1. Urine Analyzer Specifications and Compatible Urinalysis Reagent Strips

Urine Analyzer Specifications

Feature	Specifications
Methodology	Reflectance Photometer
Detection	Photosensitive diode
Throughput	Single Test Mode: 40 tests/hour
moughput	Continuous Test Mode: 120 tests/hour
Memory	Last 500 results
Strip Incubation Time	1 minute
Wavelength of Monochromatic LEDs	565 nm and 635 nm
PC Port	Standard RS232C Port (cable not included)
	Internal heat-sensitive printer (included)
Printing Capabilities	External printer (not included)
	25 Pin Parallel External Printer Port (included)
Available Languages on Screen	English and Spanish
Ambient Operating Conditions	0-40°C (32-104°F); ≤85% Relative Humidity
Ambient operating conditions	(non-condensing)
Optimum Operating Conditions	15-30°C (59-86°F); ≤75% Relative Humidity
Optimum Operating Conditions	(non-condensing)
Power Source	110-230V AC, 50/60Hz
Line Leakage Current*	0.5 mA
Weight	2.6 Kg (5.73 lbs)
Dimensions (L X W X H)	27.1 cm X 26.5 cm X 14.8 cm (10.6" X 10.3" X 5.8")
Display Dimensions (L X W)	10.6 cm X 2.8 cm (4.1" X 1.1")

This product complies with EN 61326.

Compatible Urinalysis Reagent Strips

No. of Parameters	Strip Code on Analyzer	Analytes
8	A08	Nitrite, Urobilinogen, Protein, pH, Blood, Ketone, Bilirubin and Glucose
9	A09	Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin and Glucose
10	A10	Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin and Glucose
11	A11	Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose and Ascorbic Acid

Note:

- Ensure that the type of strip selected corresponds with the strip to be used. Use of any other strip will cause incorrect results.
- Only use strips of the same brand as the analyzer to ensure proper function and accurate results.

^{*}Testing protocol and allowable limits as specified by the safety standards for laboratory equipment outlined in UL1262 and CSA 22.2 No. 151.

Appendix 2. Urinalysis Reagent Strip Specifications and Result Print-Out

According to the type of strip selected, the analyzer automatically recognizes what order the parameters are located in and automatically ranks the display and printing sequence of each parameter. Arbitrary results will always be printed automatically while the Conventional or the SI results will be printed according to the unit setting selected. Refer to **Unit Setup** on page 9.

Urinalysis Reagent Strip Parameter Table

Parameter Name (Abbreviation on Display)	Arbitrary	Conventional	SI
Leukocytes (LEU)	- ± 1+ 2+ 3+	Leu/µL 15 Leu/µL 70 Leu/µL 125 Leu/µL 500 Leu/µL	Leu/µL 15 Leu/µL 70 Leu/µL 125 Leu/µL 500 Leu/µL
Nitrite (NIT)	-+	N/A	N/A
Urobilinogen (URO)	- ± 1+ 2+ 3+	0.2 mg/dL 1 mg/dL 2 mg/dL 4 mg/dL 8 mg/dlL	3.5 µmol/L 17 µmol/L 35 µmol/L 70 µmol/L 140 µmol/L
Protein (PRO)	- ± 1+ 2+ 3+	mg/dL 15 mg/dL 30 mg/dL 100 mg/dL 300 mg/dL	g/L 0.15 g/L 0.3 g/L 1.0 g/L 3.0 g/L
рН	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0
Blood (BLO)	- ± 1+ 2+ 3+	Ery/µL 10 Ery/µL 25 Ery/µL 80 Ery/µL 200 Ery/µL	Ery/µL 10 Ery/µL 25 Ery/µL 80 Ery/µL 200 Ery/µL
Specific Gravity (SG)	1.000 1.005 1.010 1.015 1.020 1.025 1.030	1.000 1.005 1.010 1.015 1.020 1.025 1.030	1.000 1.005 1.010 1.015 1.020 1.025 1.030
Ketone (KET)	- ± 1+ 2+ 3+	mg/dL 5 mg/dL 15 mg/dL 40 mg/dL 80 mg/dL	mmol/L 0.5 mmol/L 1.5 mmol/L 4.0 mmol/L 8.0 mmol/L
Bilirubin (BIL)	1+ 2+ 3+	mg/dL 1 mg/dL 2 mg/dL 4 mg/dL	μmol/L 17 μmol/L 35 μmol/L 70 μmol/L
Glucose (GLU)	- ± 1+ 2+ 3+	mg/dL 100 mg/dL 250 mg/dL 500 mg/dL 1000 mg/dL	mmol/L 5 mmol/L 15 mmol/L 30 mmol/L 60 mmol/L
Ascorbic Acid (ASC)	1+ 2+ 3+	mg/dL 10 mg/dL 20 mg/dL 40 mg/dL	mmol/L 0.6 mmol/L 1.2 mmol/L 2.4 mmol/L

Note:

- Arbitrary:
 - All positive results except pH and Specific Gravity (SG) will be reported as 1+, 2+, or 3+.
 - Positive results for pH and Specific Gravity (SG) will be reported with the respective data.
 - Negative results for Leukocyte, Nitrite, Urobilinogen, Protein, Blood, Ketone, Bilirubin, Glucose, and Ascorbic Acid will be reported as "-".
- Conventional or SI:
 - All positive results except Nitrite (NIT) will be reported with the respective data in front of the units.
 - All negative results except Nitrite (NIT) will be reported with a blank space in front of the units.
 - Results for Nitrite (NIT) will not be reported in Conventional or SI units but will be reported in Arbitrary units.

Result Print-Out

The date, time, and clinical number will be printed along with the test results in Arbitrary units. The test results in either Conventional or SI units will be printed as well depending on the unit selection.

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Appendix 3. Catalog

Product Name	Catalog Number	Components	Quantity
		U120 Urine Analyzer	1
	U111-101	Strip Holder	1
U120 Urine Analyzer		Printer Paper Rolls	2
0 120 Offile Affaiyzer		Fuses (2.0A)	2
		Power Cord	1
		Instruction Manual	1
Printer Paper Rolls	U121-101	Printer Paper Rolls	4

Appendix 4. Index of Symbols

<u> </u>	Attention, see instructions for use	<u>~~</u>	Manufacturer	EC REP	Authorized Representative
IVD	For <i>In vitro</i> diagnostic use only	LOT	Lot Number	REF	Catalog #
0°C	Store between 0-40°C	Σ	Tests per kit	SN	Serial number
誉	Keep away from sunlight and heat	\searrow	Use by	IOIOI	Serial port
Ť	Keep dry		Fragile, handle with care	↑↑ UP	This side up

Appendix 5. Warranty

Please complete the warranty card included in the packaging and mail it to your local distributor to register your purchase within 30 days of purchase.

For your records, write the purchase date of your starter kit here:

Note: This warranty applies only to the analyzer in the original purchase, and does not apply to the other materials included with the analyzer.

ACON Laboratories, Inc. warrants to the original purchaser that this analyzer will be free from defects in materials and workmanship for a period of 90 days (3 months) from the later of the date of original purchase or installation (except as noted below). During the stated 90-day period, *ACON* shall replace the unit under warranty with a reconditioned unit or, at its option, repair at no charge a unit that is found to be defective. *ACON* shall not be responsible for shipping charges incurred in the repair of such an analyzer.

This Warranty is subject to the following exceptions and limitations:

This warranty is limited to repair or replacement due to defects in parts or workmanship. Parts required which were not defective shall be replaced at additional cost, and *ACON* shall not be required to make any repairs or replace any parts that are necessitated by abuse, accidents, alteration, misuse, neglect, failure to operate the analyzer in accordance with the operations manual, or maintenance by anyone other than *ACON*. Furthermore, *ACON* assumes no liability from malfunction or damage to analyzers caused by the use of strips other than strips manufactured by *ACON*. *ACON* reserves the right to make changes in the design of this analyzer without obligation to incorporate such changes into previously manufactured analyzers.

Disclaimer of Warranties

This warranty is expressly made in lieu of any and all other warranties express or implied (either in fact or by operation of law) including the warranties of merchantability and fitness for use, which are expressly excluded, and is the only warranty given by ACON.

Limitations of Liability

In no event shall ACON be liable for indirect, special or consequential damages, even if ACON has been advised of the possibility of such damages.

For warranty service, please contact your local authorized ACON distributor.

Mission™ U120 Urine Analyzer Warranty Card

Please complete this warranty card and mail it to your local distributor to register your purchase within 30 days of purchase. Refer to **Appendix 5. Warranty** in the Instruction Manual, for details and terms of the product warranty.

Date of Purchase	Purchaser	Analyzer Serial Number (e.g. SN 0000000. See label on back of analyzer)
Organization Name		Address
Telephone Number		Email address

